NATIONAL ADMINISTRATIVE REGISTER · JULY 6, 2005

GENE THERAPY

BFAD BUREAU CIRCULAR NO. 14, S. 2005, July 06, 2005

Read online (full-text search, related cases, audio case brief): https://batas.org/library/24f6490f0102/

Rationale:

Genes are biological units of heredity. Genes determine evident traits like skin or eye color as well as less obvious characteristics like blood type, etc. A gene is part of deoxyribonucleic acid (DNA) molecule. Humans possess 50,000 to 100,000 genes. Genes carry instructions that permit the cells to produce specific proteins such as enzymes. When proteins are created, cells utilize another molecule, ribonucleic acid (RNA) to translate genetic information stored in DNA.

Only certain genes in a cell are active at any given time. As cells mature, many genes become permanently inactive. The kind of active and inactive genes in a cell and the resulting protein composition determine what type of cell it is, what this cell is capable of doing and what it cannot do. Defects in genes can result in disease.

Gene therapy is an experimental treatment that involves introducing genetic material (DNA or RNA) into a person's cells to treat or prevent disease. Gene therapy is being studied in clinical trials (research studies involving humans) for many different cancers and other diseases. Gene therapy is not available outside of these trials.

The primary function of BFAD, in the protection of health and welfare of Filipinos, is to ensure that drugs, medical devices and biological products are safe and effective before these are prescribed by doctors and used by patients. BFAD places under its authority the regulation of all gene therapy products and studies.

Scope of regulation:

Standards of safety, efficacy, purity and potency must be complied with:

List of requirements to be submitted for Investigational New Drug

1. For locally manufactured product, License to Operate as drug manufacturer

2. Certificate of Current Good Manufacturing Process local or country of origin

3. Summary of manufacturing process including quality control and assurance

4. General Information:

- Name of product
- Active Ingredient(s)

- Official Chemical Name (if applicable)

Turn this case into an audio lecture - facts, issues, ruling and doctrine - at batas.org

- Molecular Chemical Formula
- Amount per unit dose

- Dosage Form
- Recommended dosage and frequency of administration
- Indication/s or recommended use/s
- Route of administration

5. Laboratory analysis and tests demonstrating safety of gene therapy products

6. Animal Study Protocol and results of tests

7. If clinical trials (study of gene therapy in humans) are yet to be conducted, company must secure permit to conduct appropriate (Phases 1, 2 or 3) study. The study product shall be considered an Investigational New Drug (IND).

8. Study protocol must be submitted. The protocol explains how the study will be conducted, what patients to include and exclude how the drug will be administered, the benefits that may be gained, determination of efficacy, possible risks that maybe encountered and measures by which patients are to be protected. The protocol should also provide additional data in support of study. Such study should adhere to principles of Declaration of Helsinki, Good Clinical Practice (GCP, 1997) and applicable Philippine laws and regulations.

9. Informed Consent should be obtained from persons participating in the study. Part of the information provided should include the potential risks and benefits.

IND approval by BFAD shall be based on careful review by its advisor-consultants before a study can be started. The consultants shall include microbiologists, molecular biologists, pharmacologists, toxicologists and immunologists

Duties of this panel of experts:

1. determine if gene therapy is appropriate for the disease

2. determine if such gene therapy is effective and safe, taking into account the protection of human subjects in the study

Manufacturer must secure approval of study protocol from the Hospital Institutional Ethics Review Board, a committee consisting of scientific, legal and medical advisors, religious and consumers. Focus is on the protection of persons participating in the study.

In keeping with the mandate of BFAD, the safety of patients is a primary concern. BFAD requires that manufacturers and medical researchers to be committed to the protection of patient and consumer welfare, to use highest quality experimental products, practice good clinical practice and accurately communicate information to BFAD and patients concerned.

Adopted: 6 July 2005

(SGD.) PROF. LETICIA BARBARA B. GUTIERREZ, MS
Director

Bar review courses, mock exams and a study planner that keeps you on pace - batas.org

ABOUT BATAS.ORG

Study smarter at BATAS.org

The Philippine bar review and law-school companion built around how your brain actually remembers.

The complete Philippine law library - free for everyone.

More than 100,000 Supreme Court decisions, Republic Acts, and executive issuances - full-text searchable, browsable by category and year, and always free. No paywall, no login. This PDF came from it.

Audio case-brief lectures.

Any decision becomes a podcast-style lecture - facts, issues, ruling, and doctrine - with read-along highlighting and a hands-free presentation mode. Study while commuting, working out, or resting your eyes.

Bar review built on the science of memory.

Complete, sequenced courses for all eight bar subjects, narrated like podcasts and reinforced with retrieval practice and spaced review - the study techniques with the strongest evidence behind them.

The full law-school curriculum.

One subscription unlocks the entire J.D. curriculum - every subject, every lesson, with your progress tracked down to the paragraph so you can pick up exactly where you left off, on any device.

Mock exams that tell you where you stand.

Timed multiple-choice exams graded instantly, with per-subject score breakdowns and focus suggestions that point you at your weakest topics first.

A study planner that keeps you on pace.

Set your schedule and BATAS tells you every day whether you are on track for bar day - and exactly which lesson to take next.

Start free at https://batas.org

The law library is free forever - and your first lesson is one click away.

The text of this document is an official public record and remains in the public domain. Formatting, presentation, and compilation © 2026 batas.org.

Downloaded free from the batas.org Law Library. Share it freely - the library is free for every law student, bar reviewee, and practitioner.